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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,793	07/24/2003	Mark B. Lyles	068351.0138	1223

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EXAMINER

SCHNIZER, RICHARD A

ART UNIT PAPER NUMBER

1635

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/626,793

Applicant(s)

LYLES, MARK B.

Examiner

Richard Schnizer, Ph. D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-51 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/17/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

An information disclosure statement was received and entered on 9/17/03.

Claims 1-51 are pending and under consideration in this Office Action.

The priority date for this application is 7/24/03.

Claim Objections

Claim 17 is objected to because "maxtix" is misspelled.

Claim 35 is objected to because "and" at line 3 of page 33 should be deleted and reinserted at the end of line 4 of page 33 (after "nucleic acid;").

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 10, 13-24, 27, 32, 40, 42, and 45-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3, 5-7, 14-17, 19-24, 45-47, and 49-51 are indefinite because it is unclear what are the metes and bounds of "modified nucleic acid". One of skill in the art is given no reference point from which to determine what constitutes a modification. In contrast claims 8, 25, 35 and dependents are method claims in which a starting material (nucleic acid) is modified. These claims are not included in the rejection because one of skill in the art has a reference point (the starting material) with which to compare. It is

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unclear what is the intended breadth of the claims. For example, all polynucleotides could be considered to be "modified" by the addition of their 3' base during polymerization, or the term could be interpreted much more narrowly, as in e.g. claim 4.

The term "small" in claims 4, 10, 18, 27, 40, and 48 is a relative term which renders the claim indefinite. The term "small" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The parameter of "molecule" is rendered indefinite such that one of skill in the art cannot know the size of the molecules to which the claims are limited.

Claims 7, 13, 20, 32, 42, and 51 are indefinite because they identify as copolymers each of polylactic acid, polyglycol alginate, polyglycolic acid, and cellulose acetate. However, each of these compounds is a polymer of identical monomers, not a copolymer (i.e. not composed of more than one type of monomer). Only the recited species of "poly amino acids", "polysaccharides", "hyaluronic acid", and "collagen" embrace copolymers.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4-10, 12-14, 17-20, 23-27, 31-35, 38-45, and 48-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Levy et al (US Patent 6,395,029).

Levy taught compositions for sustained delivery of nucleic acids, including sutures comprising matrices comprising nucleic acids. See e.g. claim 19 at column 40. The nucleic acid is modified by addition of a biodegradable polycationic peptide such as polylysine. See claim 8. The composition may also comprise a copolymer such as polylactate/polyglycolate. See claim 15. The suture is considered to be a filament, as required by instant claim 8. The nucleic acid may encode a protein such as a wound healing factor. See claim 12. Regarding claims 35, 45, and dependents, the isolated nucleic acid of Levy is considered to be a nucleic acid biomaterial in itself, which is a biodegradable polymer.

Claims 1-5, 14-18, 25-28, 45, and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Bennett et al (US patent 6,096,722), as evidenced by Burkoth et al (US Patent 6,893,664).

Bennett taught antisense molecules comprising a 2'methyl or ethyl modification. See abstract and column 11, lines 5-11, 30, and 51. Bennett also taught an oligonucleotide preparation method involving multiple lyophilization steps in which

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aqueous oligonucleotide solutions are frozen and lyophilized. See column 48, lines 1-34. That this method results in a matrix material is evident from Burkoth who taught that lyophilization is a common method for preparing particulate biopharmaceuticals, such as nucleic acids, and involves rapid freezing at a very low temperature, followed by rapid dehydration by sublimation in a high vacuum. "This technique typically yields low-density porous particles having an open matrix structure." See column 14, lines 31-38. The matrix is considered to be at least 50% nucleic acid by weight and volume because it consists only of nucleic acid. Claims 1-5 are included in this rejection because the term "suture material" was interpreted to embrace materials from which sutures (i.e. filaments suitable for sewing parts in a living body) could be made. Absent evidence to the contrary, the material of Bennett could be dissolved, formed into a gel, and passed through a spinneret into a precipitating medium as taught in the instant specification at page 20, lines 10-17.

Claims 14, 17-19, 22-27, 29, 31, 33, and 34 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Richard (US Patent Application Publication 20030044514).

Richard taught methods of coating stents, catheters, and shunts with nucleic acid expression vectors encoding wound healing factors such as angiogenic factors, fibroblast growth factors, vascular endothelial growth factor, epidermal growth factor, and others. Coating is performed through the use of supercritical carbon dioxide and can be performed so as to form a foamed or porous morphology. The nucleic acids are

modified by attachment of a targeting peptide or cationic vector. See entire document, especially paragraphs 1, 5, 33, and 34. The targeting peptides are considered to be copolymers because they are polymers of more than one type of amino acid monomer. This broad interpretation of the term "copolymer" appears to be consistent with the specification and claims as filed inasmuch as claim 20 defines the polypeptide collagen as a copolymer. The stents of Richard are considered to be tissue scaffolds because a stent is a scaffold that supports tissue.

Claims 14, 21, 25, 26, 30, 45, and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Levy et al (US Patent 6,333,194).

Levy taught methods of making hydrogel matrices comprising modified nucleic acids. See e.g. abstract, and paragraph bridging columns 13 and 14.

Claims 35-43 and 45-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolff et al (US Patent 6,093,701).

Wolff taught a method for making a nucleic acid biomaterial comprising isolating modifying a nucleic acid with 5-12 rhodamine molecules/kb, and conjugating the rhodamine-modified nucleic acid with a nuclear localization signal at a peptide:DNA weight ratio of between 0.18: and 0.67:1. See abstract, column 7, lines 25-47, column 10, lines 21-29, and sentence bridging columns 12 and 13. So Wolff taught a biomaterial that is at least 50% DNA by weight and volume, and comprises a nucleic acid that is at least 95% DNA. The peptide nuclear localization signal is considered to

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be biodegradable. The polymer is considered to be a drug carrier because the DNA can encode a polypeptide for expression within a target cell.

Conclusion

No claim is allowed. Claim 11 is objected to because it depends from a rejected claim, but would be allowable if rewritten in independent form including all of the limitations of the claim from which it depends.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang, can be reached at (571) 272-0811. The official central fax number is 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Richard Schnizer, Ph.D.